



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
IMPORTER OF CONTROLLED SUBSTANCES
NOTICE OF APPLICATION
FRESENIUS KABI USA, LLC.

Pursuant to 21 CFR 1301.34(a), this is notice that on November 2, 2012, Fresenius Kabi USA, LLC., 3159 Stanley Road, Grand Island, New York 14072, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Remifentanyl (9739), a basic class of controlled substance listed in schedule II.

The company plans to import this controlled substance for product development and preparation of stability batches.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: SIGNED December 31, 2013

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